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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,657	08/25/2003	William Cohn	301492.1047-119	2131

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EXAMINER
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BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/647,657

Applicant(s)

COHN ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 25 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <del>1-22-04</del> <u>1-22-04</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7 and 9-11 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 7, 21, 22, 23, 26, 27, 29, and 30 of U.S. Patent No. 6,610,071. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of application is broadened by removing the method step of placing the suturing through a cuff in a prosthetic device. It would be known to one skilled in the art to broaden the method by not inserting the suture into the cuff. Regarding Claim 5 of the application, it is not patentably distinguishable over Claims 21 and 22 or Claims 29 and 30 of the patent

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because a double braided suture is claimed in Claims 22 and 29 and the application claims a visual indicator, while the patent claims a color, which is more specific than the application.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 22 January 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**6. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965.**

7. Claim 1: Phillips teaches a method of implanting an artificial valve including placing a first suture (26) through tissue (40) at a first position using a first needle (32); placing a second needle (34) through tissue (40) at a second position, and repeating this processes using additional needles. The prosthetic device (16) is attached to the annulus body tissue (40) using needles in the suturing system and is then secured to the body (column 2, lines 15-46). Phillips'965 does not teach additional needles, however it would have been obvious to one skilled in the art at the time of the invention to use additional needles to be attached to the additional sutures taught by Phillips'965 (column 2, line 20) because Philips'965 teaches the use of multiple suture/needle devices in his procedure.

8. Claims 2-4: Phillips'965 discloses the use of different color sutures to aid in identifying individual sutures (column 1, lines 23-57).

**9. Claim 5, 6, 7, 8, 10, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soviet Union Patent 513696 (SU'696) in further view of Phillips (US Patent 4,932,965).**

10. Claims 5, 6 and 8: SU'696 teaches a suturing device containing at least three needles (2) with at least one needle being attached to a double stranded suture (6, 7); each suture strand extends between a pair of connected needles. The needles (2) are removable from the suture strands (Derwent Abstract, line 5).

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11. Claim 5: SU'696 does not teach the use of a visual indicator to identify the individual suture strands. Phillips'965 teaches the use of a valve sewing ring containing pairs of sutures with needles attached in which each suture pair is color coded between with two different colors to aid in identification of the individual sutures (column 1, lines 23-42). Since Phillips'965 teaches a way to identify suture pairs by using different colors, it would have been obvious to further identify individual sutures using different colors as well. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use different colored sutures in order to identify each individual suture in a suture pair.

12. Claim 7: SU'696 teaches that suturing device contains three needles (2) that are associated with at least two sutures strands (5, 6, 7, 8).

13. Claims 10, 11, and 14: Phillips'965 teaches a cuff (16) through which sutures (26) are threaded (column 2, lines 16-32) during aortic valve replacement surgery (column 1, lines 1-20). The cuff is threaded before surgery to reduce implantation time (column 1, lines 23-42). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use the device taught by SU'696 and Phillips'965 to suture a cuff prior to surgery in order to reduce implantation time and reduce the risks of the surgery.

**14. Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Ablaza (US Patent 4,632,113).**

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15. Claim 9: SU'696 and Phillips'965 teach the limitations of Claim 9, except for the use of suture pads.

16. Ablaza'113 teaches the use of suture pads (12 in Figure 1, or 20 in Figure 2) attached to suture strands (18) because they prevent any movement between the suture and the pad, and reduce the tendency of the suture to tangle; further, Ablaza'113 teaches that suture pads are used as anchors when the suturing device is used to close a slit in an aorta (column 2, lines 63-68 and column 3, lines 1-8). Therefore it would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by SU'696 and Phillips'965 with a suture pad because they allow the suture to act as an anchor when closing the aorta.

**17. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Alpern, et al. (US Patent 5,284,293).**

18. SU'696 and Phillips'965 teach the limitations of Claim 12, except for the use of a package for housing the suture device. Alpern teaches that it is well known in the art to use a dispenser to house suturing devices prior to use because they are packaged in a sterile manner and it is beneficial to be able to see the quantity of suturing devices in a box (column 1, lines 1-34). Therefore it would have been obvious to one skilled in the art at the time the invention was made to place sterile packaged sutures in a box prior to use because this makes it easier for doctors to see the quantity of suturing devices in the box.

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**19. Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Ovil, et al. (US Patent 4,702,250).**

20. SU'696 and Phillips'965 teach the limitations of Claim 13, except for a mechanical suture placement device.

21. Mechanical suture placement devices are well known in the art and it would have been obvious to include a mechanical suture placement device to place the sutures. Furthermore, Ovil'250 teaches the use of a mechanical suture placement apparatus because suture placement is time consuming and there is a risk of entangling the sutures. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a mechanical suture placement device to place the sutures because it is easier for the surgeon and reduces the risk of entanglement.

### ***Conclusion***

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES  
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